

LIBELED: 11-21-56, N. Dist. Okla.

CHARGE: 501 (b)—the strength of the tablets, while held for sale, differed from the standard for *halazone tablets* set forth in the National Formulary.

DISPOSITION: 12-7-56. Default—the tablets were destroyed, and the other items in the *first aid kits* were released to the owner.

5294. First aid kits. (F. D. C. No. 39427. S. No. 58-361 M.)

QUANTITY: 227 *first aid kits*, each containing 1 btl. of *halazone tablets*, at Denver, Colo.

SHIPPED: 2-16-56 and 7-25-56, from St. Louis, Mo.

LABEL IN PART: (Btl.) "Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. ($\frac{1}{16}$ grain) of Halazone with Sodium Carbonate, Sodium Chloride, and Boric Acid."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 30 percent to 129 percent of the declared amount of halazone, whereas the National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 8-23-56, Dist. Colo.

CHARGE: 501 (b)—the strength of the tablets, while held for sale, differed from the standard set forth in the National Formulary for *halazone tablets*.

DISPOSITION: 1-22-57. Default—destruction.

5295. First aid kits. (F. D. C. No. 39455. S. No. 41-443 M.)

QUANTITY: 116 first aid kits, each containing 1 btl. of *halazone tablets*, at Rochester, N. Y.

SHIPPED: 7-30-56, from New York, N. Y.

LABEL IN PART: (Btl.) "100 Water Purification Tablets * * * Halazone * * * Each tablet contains 0.004 Gm. ($\frac{1}{16}$ grain) of Halazone with Sodium Carbonate, Sodium Chloride and Boric Acid [or "with sodium borate and chloride"]."

RESULTS OF INVESTIGATION: The *halazone tables* were war surplus stock which had been manufactured in New Jersey and Illinois. Analysis showed that the tablets contained from 29 percent to 88 percent of the declared amount of halazone, whereas the National Formulary provides that *halazone tablets* contain not less than 90 percent of the declared amount of halazone. The tablets in some bottles were stuck together and crumbling, which rendered them unfit for their intended use.

LIBELED: 9-7-56, W. Dist. N. Y.

CHARGE: 501 (b)—the strength and quality of the tablets, while held for sale, differed from the standard set forth in the National Formulary for *halazone tablets*.

DISPOSITION: 10-15-56. Default—destruction.

5296. Clinical thermometers. (F. D. C. No. 39392. S. Nos. 17-250 M, 19-556 M, 25-386 M, 29-999 M, 30-447 M, 47-488 M.)

INFORMATION FILED: 2-15-57, E. Dist. N. Y., against Cardinal Thermometer Co., Brooklyn, N. Y.

SHIPPED: Between 4-15-55 and 2-21-56, from New York to Virginia, Ohio, Illinois, Washington, and New Jersey.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind—Oral [or "Stubby"]."

ACCOMPANYING LABELING: Leaflet entitled "Certificate of Accuracy For Clinical Thermometers."

CHARGE: 501 (c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since it purported and was represented to comply with the requirements for accuracy specified in Commercial Standard CS1-52 issued by the National Bureau of Standards of the Department of Commerce, whereas the article failed to comply with such requirements; and 502 (a)—the following statements in the above-mentioned leaflet were false and misleading: "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1-52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce."

PLEA: Guilty.

DISPOSITION: 12-19-57. \$300 fine.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

5297. Sustamin tablets. (F. D. C. No. 36843. S. No. 80-668 L.)

QUANTITY: 41 display ctns., 6 50-tablet pkgs. each, and 9 display ctns., 6 100-tablet pkgs. each, at Philadelphia, Pa.

SHIPPED: 4-20-54, from New York, N. Y., by Protam Pharmacal Co.

LABEL IN PART: (Ctn.) "Sustamin 2-12 * * * 12 Hour Continuous Medication With Only 2 Tablets * * * New Medical Discovery"; (pkg.) "Sustamin Tablets 2 Tablets - 12 Hour Medication * * * Active Ingredients Each tablet contains Sodium Salicylate Acetophenetidin 2 gr., Anhydrous Caffeine."

ACCOMPANYING LABELING: Circular entitled "Sust-A-Gram * * * New Hospital Proved Sustamin 2-12 Stops Pains of Arthritis-Rheumatism, Bursitis, Neuritis, Sciatica, Lumbago."

LIBELED: 6-23-54, E. Dist. Pa.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis, rheumatism, bursitis, sciatica, lumbago, swelling, and inflammation, and for providing increased mobility to impaired joints.

DISPOSITION: On 9-24-54, John T. and Harriet Andreadis, d/b/a Protam Pharmacal Co., filed a claim and an answer denying the misbranding charge above. The Government filed interrogatories on 2-8-55, and the claimant filed objections to the interrogatories on 3-18-55. On 9-30-55, the claimant's objections to certain interrogatories were sustained in part, and the court ordered the claimant to answer the other interrogatories. The claimant filed answers to the interrogatories as ordered; and, on 5-2-56, the Government filed a motion for summary judgment, which was denied on 7-9-56, as the court found that the record showed substantial questions of fact existed.

*See also Nos. 5287, 5288, 5291, 5296.